JUL 1 3 2004

K040782

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(Submitted in accordance with the requirements of 21 CFR 807.3)

Contact information:

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Date: March 22, 2004

Device/Trade Name: N-Vivo Calcium Score

Common/Usual Name: CT Calcium Scoring Software

Classification Name: No Classification has specifically been issued for calcium scoring, however it may be classified as an accessory to an imaging device. 21CFR892.1750

Marketed Devices:

N-Vivo™ Calcium Score operating on the IA Chassis is substantially equivalent to currently marketed devices including: K972903 UltraAccess Workstation with Cardiac Score, K990241 AccuView with AccuScore, K891931 QCT-Lung nodule analysis.

Device Description:

A software package operating on a PC which facilitates non-invasive measurements of vascular calcified plaques. The device provides Agaston, Volume and Mass Scores using Phantom Calibrated CT images.
The key features include:

- Hybrid calibration with external phantom and invivo blood pool reference.
- Plaque definition which include statistical and calibrated thresholds for a calcium mass measurement.
- Artery trace which segments regions of the heart that include the coronary arteries and aorta.
- Automated identification, quantification, and scoring of vascular calcium.
- PC workstation with web browser based interface which includes database, Dicom reports, Serial graphs and QA module.

Indications for Use:

Calcium scoring of calibrated CT images to provide quantitative measures of calcium content in the coronary arteries and aorta. The software is intended to be used under the supervision

of trained physicians to monitor progression/regression of vascular calcium which may be useful in the prognosis of Cardiovascular disease.

Adverse Effects on Health:

Neither the software package nor the presence of the phantom during CT scanning will have any adverse effects on health. The calibration and software analysis improves the performance of calcium measurements from reconstructed CT images. Any potential safety risks associated with this product are not materially different form those of currently marketed devices for post processing image analysis. The PC hardware is "off-the-shelf" and complies with applicable safety standards for PC hardware and peripherals.

Conclusions:

The N-Vivo™ Calcium Score software operating on the IA chassis has been developed and validated by acceptable standards for the industry and these required by the FDA. It is substantially equivalent to calcium scoring products currently in the market.

Signature

Ben Arnold

Printed Name

President

Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 3 2004

Ben A. Arnold, Ph.D.
President
Image Analysis, Inc.
1380 Burkesville Street
COLUMBIA KY 42728

Re: K040782
Trade/Device Name: N-Vivo™ Calcium Score on Image Analysis Chassis PC
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: June 22, 2004
Received: June 24, 2004

Dear Dr. Arnold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K040782

Device Name: N-Vivo™ Calcium Score on Image Analysis Chassis PC

Indications for Use:

N-Vivo™ Calcium Score is a calibrated software program for non-invasive identification and quantification of calcified plaques in the coronary arteries and aorta using CT images. The software runs on a standard PC with basic image processing, database and reporting functions.

N-Vivo™ may be used to monitor progression/regression of calcium which may be useful in the prognosis of cardiovascular disease.

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040782